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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/042,202	01/11/2002	Adrian Vivian Sinton Hill	2002_0026	6969

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EXAMINER	
SCHWADRON, RONALD B	
ART UNIT	**PAPER NUMBER**
1644	

DATE MAILED: 05/12/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/042,202	HILL ET AL.	
	Examiner	Art Unit	
	Ron Schwadron, Ph.D.	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 12-18 is/are pending in the application.

4a) Of the above claim(s) 13,15,17 and 18 is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 12,14,16 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☒ Certified copies of the priority documents have been received in Application No. 08/714,175.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

1. Applicant's election of Group I in the reply received 11/2/2004 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

2. Claim 18 is withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made without traverse in the reply filed on 9/19/2002.

3. Applicant's election of the peptide SEQ ID NO:1 in the reply received 2/17/2005 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

4. Claims 13,15,17 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species, there being no allowable generic or linking claim. Election was made without traverse in the reply filed on 9/19/2002.

5. Claims 12,14,16 are under consideration.

6. Applicants need to update the status of all US applications disclosed in the specification.

7. The abstract of the disclosure does not commence on a separate sheet in accordance with 37 CFR 1.52(b)(4). A new abstract of the disclosure is required and must be presented on a separate sheet, apart from any other text.

8. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

9. Claim 16 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The specification is not enabling for the claimed vaccine. The specification does not disclose how to use the instant invention for the in vivo treatment of malaria infection in humans. Applicant has not enabled the breadth of the claimed invention in view of the teachings of the specification because the use for the instant invention disclosed in the specification is the in vivo treatment/prevention of malaria infection in humans. The state of the art is such that is unpredictable in the absence of appropriate evidence as to how the instant invention could be used for the in vivo treatment/prevention of malaria infection in humans.

Judge Lourie stated in Enzo Biochem Inc. v. Calgene Inc. CAFC 52 USPQ2d 1129 that:

The statutory basis for the enablement requirement is found in Section 112, Para. 1, which provides in relevant part that:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same. . . .35 U.S.C. Section 112, Para. 1 (1994). "To be enabling, the specification of a patent must teach those skilled in the art how to make and use the full scope of the claimed invention without 'undue experimentation.' " Genentech, Inc. v. Novo Nordisk, A/S , 108 F.3d 1361, 1365, 42 USPQ2d 1001, 1004 (Fed. Cir. 1997) (quoting In re Wright , 999 F.2d 1557, 1561, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993)). Whether claims are sufficiently enabled by a disclosure in a specification is determined as of the date that the patent application was first filed, see Hybritech, Inc. v. Monoclonal Antibodies, Inc. , 802 F.2d 1367, 1384, 231 USPQ 81, 94 (Fed. Cir. 1986), which in this case is October 20, 1983 for both the '931 and '149 patents.

We have held that a patent specification complies with the statute even if a "reasonable" amount of routine experimentation is required in order to practice a claimed invention, but that such experimentation must not be "undue." See, e.g., Wands , 858 F.2d at 736-37, 8 USPQ2d at 1404 ("Enablement is not precluded by the necessity for some

experimentation . . . . However, experimentation needed to practice the invention must not be undue experimentation. The key word is 'undue,' not 'experimentation.' ") (footnotes, citations, and internal quotation marks omitted). In In re Wands , we set forth a number of factors which a court may consider in determining whether a disclosure would require undue experimentation. These factors were set forth as follows:
(1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims.
Id. at 737, 8 USPQ2d at 1404. We have also noted that all of the factors need not be reviewed when determining whether a disclosure is enabling. See Amgen, Inc. v. Chugai Pharm. Co., Ltd. , 927 F.2d 1200, 1213, 18 USPQ2d 1016, 1027 (Fed. Cir. 1991) (noting that the Wands factors "are illustrative, not mandatory. What is relevant depends on the facts.").

Regarding Wands factors 4,5,7,8, the claimed inventions are drawn to a vaccine composition that can be used to treat/prevent malaria. The substantial/real life use for the claimed inventions are preventing and treating malaria infection. There is currently no known vaccine containing a malarial peptide for treating or preventing malaria (see Ritchie et al.). Ritchie et al. states: ""But the vaccine, which has been promised to be 'just around the corner' for many years, remains elusive." (see abstract). Thus, there is no current malarial vaccine. Thus, the state of the art is that it is highly unpredictable whether any particular malarial derived peptide could be used as a vaccine to treat malaria in humans. As per Wands factor (8), the claimed inventions are used for preventing and treating malarial infection. It is also noted that Ritchie et al. indicate that successful malarial vaccine would have to stimulate antibody responses (see page 697, first column, second paragraph) wherein there is no evidence of record that the peptides recited in the claims have such a property. Ritchie et al. also disclose that particular combinations of malarial peptides will probably be required wherein the nature of such peptide combinations has not yet been elucidated (see page 696, second column and page 697, first column). Ritchie et al. indicate that there are at least 5000 known malarial proteins (see page 698, second column).

Regarding Wands factors 1-3,7 there is no disclosure in the specification of experimental data indicating that the claimed peptide can be used to prevent or treat malarial infection in vivo in humans. Thus, use of a particular peptide for treatment/prevention of malarial infection is an unpredictable field where extensive experimentation and guidance would be required to use the claimed vaccine or pharmaceutical composition in vivo in humans. The specification provides no evidence predictive of whether the claimed invention could be used in vivo in humans to treat/prevent malarial infection. Regarding Wands factor 6, the relative skill of those in the art is high (eg. Ph.D. or M.D.).
Undue experimentation would be required of one skilled in the art to practice the instant invention using the teaching of the specification. See In re Wands 8 USPQ2d 1400(CAFC 1988).

10. Claims 12,14,16 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

a) There is no support in the specification as originally filed for the scope of claim 12 that recites "said amino acid sequence of SEQ ID No.1 being capable of binding to human leukocyte antigen HLA-A2 when said sequence is present in said isolated peptide". Said phrase implies that the peptide of 10- 100 amino acids containing SEQ ID No. 1 would bind HLA-A2 and this is not disclosed in the specification as originally filed. There is no support in the specification as originally filed for the scope of the claimed invention (eg. the claimed invention constitutes new matter).

b) There is no support in the specification as originally filed for the scope of claim 12 that recites "said sequences being recognized by cytotoxic T lymphocytes (CTLs) from individuals currently or previously infected by Plasmodium". The specification does not disclose that said peptide would be recognized by individuals currently or previously infected by Plasmodium. The specification is limited to TRAP antigen derived peptides from Plasmodium falciparum, not Plasmodium per se (which would encompass

other strains of Plasmodium such as vivax, etc). Also, the peptide of SEQ ID No 1 is disclosed in the specification as HLA A2 restricted so it would only be recognized by CTL that were from HLA-A2 positive individuals.
There is no support in the specification as originally filed for the scope of the claimed invention (eg. the claimed invention constitutes new matter).

c) There is no support in the specification as originally filed for the scope of claim 12 that recites "immunogenicity enhancing lipid tail". The specification discloses use of a lipid tail that can "enhance CTL induction in vivo" (see page 2, lines 23-25). However the specification does not disclose the scope of the claimed invention which encompasses lipid tails which can enhance immunogenicity per se (eg. other than CTL induction in vivo, for example enhances B cell responses). There is no support in the specification as originally filed for the scope of the claimed invention (eg. the claimed invention constitutes new matter).

d) There is no support in the specification as originally filed for the scope of claim 16 that recites "pharmaceutically acceptable carrier". The specification discloses use of the claimed peptide with an adjuvant (see page 9), but does not disclose the scope of the claimed invention which constitutes use of nonadjuvant pharmaceutically acceptable carriers. There is no support in the specification as originally filed for the scope of the claimed invention (eg. the claimed invention constitutes new matter).

11. Claims 12,14,16 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The specification is not enabling for the peptide of claim 12 wherein "said amino acid sequence of SEQ ID No.1 being capable of binding to human leukocyte antigen HLA-A2 when said sequence is present in said isolated peptide" and wherein "said sequences being recognized by cytotoxic T lymphocytes (CTLs) from individuals currently or previously infected by Plasmodium".
Judge Lourie stated in Enzo Biochem Inc. v. Calgene Inc. CAFC 52 USPQ2d 1129 that:

The statutory basis for the enablement requirement is found in Section 112, Para. 1, which provides in relevant part that:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with

which it is most nearly connected, to make and use the same. . . .35 U.S.C. Section 112, Para. 1 (1994). "To be enabling, the specification of a patent must teach those skilled in the art how to make and use the full scope of the claimed invention without 'undue experimentation.' " Genentech, Inc. v. Novo Nordisk, A/S , 108 F.3d 1361, 1365, 42 USPQ2d 1001, 1004 (Fed. Cir. 1997) (quoting In re Wright , 999 F.2d 1557, 1561, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993)). Whether claims are sufficiently enabled by a disclosure in a specification is determined as of the date that the patent application was first filed, see Hybritech, Inc. v. Monoclonal Antibodies, Inc. , 802 F.2d 1367, 1384, 231 USPQ 81, 94 (Fed. Cir. 1986), which in this case is October 20, 1983 for both the '931 and '149 patents.

We have held that a patent specification complies with the statute even if a "reasonable" amount of routine experimentation is required in order to practice a claimed invention, but that such experimentation must not be "undue." See, e.g., Wands , 858 F.2d at 736-37, 8 USPQ2d at 1404 ("Enablement is not precluded by the necessity for some experimentation . . . . However, experimentation needed to practice the invention must not be undue experimentation. The key word is 'undue,' not 'experimentation.' ") (footnotes, citations, and internal quotation marks omitted). In In re Wands , we set forth a number of factors which a court may consider in determining whether a disclosure would require undue experimentation. These factors were set forth as follows:

(1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims.

Id. at 737, 8 USPQ2d at 1404. We have also noted that all of the factors need not be reviewed when determining whether a disclosure is enabling. See Amgen, Inc. v. Chugai Pharm. Co., Ltd. , 927 F.2d 1200, 1213, 18 USPQ2d

1016, 1027 (Fed. Cir. 1991) (noting that the Wands factors "are illustrative, not mandatory. What is relevant depends on the facts.").

Regarding Wands factors 4,5,7,8, the claimed inventions are drawn to a peptide that recites that "said amino acid sequence of SEQ ID No.1 being capable of binding to human leukocyte antigen HLA-A2 when said sequence is present in said isolated peptide". Said phrase implies that the peptide of 9- 100 amino acids containing SEQ ID No. 1 would bind HLA-A2. However, the art recognizes that HLA molecules generally do not bind peptides longer than 10 amino acids (see Yoon et al., page 24, first column, second paragraph). Therefore, it would not be expected that the vast majority of peptides encompassed by the range 9-100 would bind HLA-A2. Regarding the limitation "said sequences being recognized by cytotoxic T lymphocytes (CTLs) from individuals currently or previously infected by Plasmodium" the specification does not disclose that said peptide would be recognized by individuals currently or previously infected by Plasmodium. The specification is limited to TRAP antigen derived peptides from Plasmodium falciparum, not Plasmodium per se (which would encompass other strains of Plasmodium such as vivax, etc). Plasmodium vivax does not contain the sequence recited in the claims and therefore CTL against the vivax strain would not recognize said peptide. Also, the peptide of SEQ ID No 1 is disclosed in the specification as HLA A2 restricted so it would only be recognized by CTL that were from HLA-A2 positive individuals.

Regarding Wands factors 1-3,7 there is no disclosure in the specification of experimental data indicating that the claimed peptides of 11-100 amino acids would bind HLA-A2. There is no disclosure in the specification of experimental data indicating that CTL against the Plasmodium vivax strain would recognize the peptide recited in the claims. There is no disclosure in the specification of experimental data indicating the peptide of SEQ ID No 1 would be recognized by CTL other than that were derived from HLA-A2 positive individuals. Regarding Wands factor 6, the relative skill of those in the art is high (eg. Ph.D. or M.D.).

Undue experimentation would be required of one skilled in the art to practice the instant invention using the teaching of the specification. See In re Wands 8 USPQ2d 1400(CAFC 1988).

12. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

13. Claims 12,14,16 are rejected under 35 U.S.C. 102(b) as being anticipated by Hill et al. (WO 95/26982).
Regarding the prior art, for the same reasons that the claims lack written description and enablement under 35 USC 112, first paragraph, they are not entitled to priority to the parent applications to which priority is claimed.
Hill et al. disclose the peptide of SEQ. ID. No. 1 (see page 18, claim 1, tr26) with a lipid tail at the N or C terminus, wherein said lipid enhances CTL induction in vivo (see page 2, lines 23-25). The lipid tail is covalently linked (see page 9, line 30 wherein reference 21 discloses covalent linkage of the lipid tail). Hill et al. disclose said peptide with an adjuvant (see page 9). The recitation of an intended use carries no weight in the instant product claim.

14. No claim is allowed.

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ron Schwadron, Ph.D. whose telephone number is 571 272-0851. The examiner can normally be reached Monday to Thursday from 7:30am to 6:00pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan, can be reached at 571 272 0841. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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